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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BAUM, STUART F

ART UNIT

PAPER NUMBER

1638

DATE MAILED: 03/03/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application N .

09/434,837

Applicant(s)

REAM ET AL.

Examiner

Stuart F. Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 11 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3-16,25-28 and 41-48 is/are pending in the application.
- 4a) Of the above claim(s) 44 and 48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-16,25-28,41-43 and 45-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

1. The amendment filed December 11, 2002 has been entered.

Claims 1, 3-16, 25-28 and 41-48 are pending.

Claims 2, 17-24 and 29-40 have been canceled.

Claims 1, 3, 6-7 and 9-11 have been amended.

Claims 41-48 have been added.

2. Newly submitted claims 44 and 48 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claims are drawn to SEQ ID NO:7.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 44 and 48 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. Claims 1, 3-16, 25-28, 41-43, and 45-47 are examined in the present office action.
4. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.
5. Rejections and objections not set forth below are withdrawn.

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6. Claims 1, 6, 11, 43, and 47 and all subsequent dependent claims are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 6, and 11, it is unclear if the 90% limitation refers to the full length sequence of SEQ ID NO:10 or if the "90%" refers to any sequence that is at least 700 base pairs in length.

In claims 1, 6, 11, 43, and 47, line 7, the use of the indefinite article "a" makes it unclear if Applicant is claiming any number of sequences that are at least 700 base pairs in length and whose sequence comprises base pairs from SEQ ID NO:10 or if Applicant is claiming one sequence comprising all of SEQ ID NO:10.

In claims 43, and 47 it is unclear and confusing the recitation "at least 700 base pairs in length and comprises nucleotide residues between positions 1 through 1802 of the nucleic acid sequence as set forth as SEQ ID NO:10". Why is it necessary to include the limitation that the sequence be at least 700 base pairs long if it is already 1802 base pairs?

7. Claims 1, 3-16, 25-28, 41-43, and 45-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 8/6/2002. Applicant's arguments have been fully considered but they are not persuasive.

Applicants allege that the amended claims overcome the Written Description rejection by including in the claim structural features that are unique to the gene responsible for causing gall

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disease. Applicants argue that the amended claim language discloses the genotype of the claimed plants that are transformed with Applicants invention.

The Examiner disagrees that the amended claim language clarifies the genotype of the claimed plants or that the newly amended claims disclose structural features unique to Applicants invention. As discussed above, it is not clear exactly how many sequences Applicant is claiming and what is the length of the claimed sequences. Applicant is claiming sequences at least 700 bases long comprising SEQ ID NO:10 that form an untranslatable plus-sense RNA molecule, a double-stranded RNA molecule or an untranslatable double-stranded RNA molecule. Given the multitude of sequences that are encompassed by the broad claim language, it is not clear what is the genotype of the claimed plants. In addition, given the 37 C.F.R. 1.132 Declaration of Walter Ream, JR., Ph.D., only certain size sequences and sequences comprising certain segments of SEQ ID NO:10 are operative in silencing the *iaaM* of *Agrobacterium* (paragraph number 6, bridging pages 2 and 3 of the Declaration) and Applicant hasn't disclosed the identity of the functional domains, even as written in the amended claims.

8. Claims 1, 3-16, 25-28, 41-43, and 45-47 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to an isolated *iaaM* nucleic acid molecule of SEQ ID NO:10 operably linked 5' to a 35S CaMV promoter and operably linked 3' to a NOS promoter wherein the two promoters produce RNA molecules that anneal with each other to produce a double stranded RNA molecule, wherein the *iaaM* nucleic acid oncogene was modified by changing the third codon to a stop codon and introducing a frameshift mutation downstream of the introduced stop codon thereby creating additional stop

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codons in the reading frame and tobacco transformation therewith, to obtain plants that are resistant to *Agrobacterium* infection does not reasonably provide enablement for claims broadly drawn to a method comprising transforming a plant cell with a nucleic acid molecule that is at least 90% homologous to SEQ ID NO:10 or to a sequence that is at least 700 base pairs in length comprising a sequence taken from the nucleic acid sequence of SEQ ID NO:10 or a sequence that is at least 700 base pairs in length comprising a sequence taken from the nucleic acid sequence of SEQ ID NO:10 to obtain plants that are resistant to *Agrobacterium* infection. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 8/6/2002. Applicant's arguments have been fully considered but they are not persuasive.

Applicants contend that the amended claims more clearly define their invention thereby rendering moot the rejection of claims drawn to any polynucleotide.

The Examiner agrees that the amended claims are not drawn to any polynucleotide but as written still encompass sequences that have not been exemplified.

Applicants assert that a sequence exhibiting 94% sequence identity to the octopine-type Ti plasmid is capable of silencing the *iaaM* gene from a nopaline-type Ti plasmid. Applicants contend that the amended claims more clearly define their invention.

The Examiner contends that the amended claims do not make clearer the claimed invention. As discussed above, it is not clear the number of sequences Applicant is claiming, the length of the sequences or the homology of the sequences as written. In addition, based on the Declaration of Walter Ream, JR., Ph.D., it is evident that only sequences of a particular size and

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sequence constitution are capable of silencing the *iaaM* gene of *Agrobacterium* (*ibid*). Ream also states, "Moreover, a 1400 base pair construct (1-1413) that contains the Hiroyasu et al 697 base pair fragment was not capable of silencing *iaaM*" (page 4, paragraph 7).

9. Claims 1-14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hiroyasu et al (1993, Kokai Number (1993) 68574; in IDS) taken with Hartmann et al (1983, Plant Propagation, 4<sup>th</sup> edition, Prentice-Hall, Inc., Englewood Cliffs, pages 345-349, and 351-358). This rejection is maintained for the reasons of record set forth in the Official action mailed 8/6/2002. Applicant's arguments have been fully considered but they are not persuasive.

Applicants contend that Hiroyasu does not teach that any fragment except the 697 base pair fragment is required to silence *iaaM* and they have not compared other fragments to demonstrate that theirs is superior (page 14, 1<sup>st</sup> paragraph). Applicants continue by stating that they have demonstrated that not just any fragment will consistently silence the *iaaM* gene even fragments that contain all or part of the 697 base pair of the Hiroyasu et al sequence. Applicants report that they have demonstrated that the 1800 base pair *iaaM* fragment (position 9-1807 of SEQ ID NO:7) is highly effective at preventing crown gall tumor growth, only one other test fragment had an effect on tumor growth but it was less effective than the 1800 base pair fragment. Applicants conclude by stating that the lack of teaching by Hiroyasu et al regarding effective fragments other than the specifically described 697 base pair fragment, combined with the variability in the ability of *iaaM* fragments to silence *iaaM*, one of ordinary skill in the art would not have been able to predict which *iaaM* fragments would silence *iaaM* expression.

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The Examiner contends that hindsight is always right, but is not applicable when arguing obviousness. What is important, is if one would expect a reasonable expectation of success. Given peer-reviewed article of Hiroyasu et al that teach fragments of the *iaaM* gene that are 697 base pairs long are capable of silencing the *iaaM* gene of *Agrobacterium*, it would be obvious to take larger sequences for improved gene silencing. The results of the Applicants that 600 base pair sequences, or even sequences that are larger and comprise the sequences of Hiroyasu et al, do not work, are not valid arguments against the obvious rejection. In addition, the evidence for non-obviousness must be commensurate with the scope of the claims. Applicants are claiming any sequence larger than 700 base pairs but the evidence against the obviousness rejection reports that only the 1800 base pair fragment is efficient at silencing the *iaaM* gene. Applicants' amended claims that recite sequences slightly larger than the Hiroyasu et al reference, are only trying to claim around the prior art. *In re Kuhle* 188 USPQ 7 (CCPA 1975) the use of a claimed embodiment which solves no apparent problem and provides no unexpected result is deemed an obvious matter of choice.

10. No claims are allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).



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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart Baum whose telephone number is (703) 305-6997. The examiner can normally be reached on Monday-Friday 8:30AM – 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 or (703) 305-3014 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist, who may be contacted at 308-0196.

Stuart F. Baum Ph.D.

February 14, 2003

  
**ELIZABETH F. McELWAIN**  
**PRIMARY EXAMINER**  
**GROUP 1800**